

EXHIBIT

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Quest Diagnostics to Pay U.S. \$302 Million to Resolve Allegations That a Subsidiary...

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Quest Diagnostics to Pay U.S. \$302 Million to Resolve Allegations That a Subsidiary Sold Misbranded Test Kits

Quest Subsidiary, Nichols Institute Diagnostics, Pleads Guilty to Felony Misbranding

WASHINGTON, April 15 /PRNewswire-USNewswire/ -- Quest Diagnostics Incorporated and its subsidiary, Nichols Institute Diagnostics (NID), have entered into a global settlement with the United States to resolve criminal and civil claims concerning various types of diagnostic test kits that NID manufactured, marketed and sold to laboratories throughout the country until 2006, the Justice Department announced today. The payment of \$302 million will resolve these allegations and represents one of the largest recoveries ever in a case involving a medical device.

As part of the criminal resolution, NID pleaded guilty today before U.S. District Judge Sterling Johnson Jr. in Brooklyn to a felony misbranding charge in violation of the Food, Drug and Cosmetic Act relating to NID's Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay, a test that was used by laboratories throughout the country to measure parathyroid hormone (PTH) levels in patients. As part of the plea, NID will pay a criminal fine of \$40 million. Quest has also entered into a non-prosecution agreement with the United States.

As part of the civil settlement, Quest and NID will pay the United States \$262 million plus interest to resolve False Claims Act allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID that allegedly provided inaccurate and unreliable results. Quest has agreed to pay various state Medicaid programs approximately \$6.2 million to resolve similar civil claims. The company has also entered into a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services.

The United States commenced its civil and criminal investigation after the filing of a qui tam or whistleblower suit brought by Thomas Cantor. As a result of today's settlement, Mr. Cantor will share in the proceeds of the False Claims Act recovery and will receive approximately \$45 million.

The criminal resolution focuses solely on the Advantage Intact PTH Assay. As alleged in the information, there were periods of time in which the Advantage Intact PTH Assay provided elevated results. The marketing materials that NID distributed regarding the Advantage Intact PTH Assay described that product as having "excellent correlation" to the IRMA Assay. Additionally, the directional insert for the Intact PTH Assay, in a section entitled "Accuracy," described a study in which the IRMA Assay and the Advantage Intact PTH Assay produced nearly identical results when used to test PTH levels in samples of human blood. Contrary to the claims in NID's directional inserts and marketing materials, however, in about May 2000, and at various times thereafter, NID was aware that the Advantage Intact PTH Assay was not consistently providing results that were equivalent to those of the IRMA Assay.

Additionally, during some of the periods of time after May 2000, NID was also aware that the Advantage Intact PTH Assay provided elevated PTH results. Nonetheless, NID continued to indicate, in its directional inserts and marketing materials, that the Advantage Intact PTH Assay and the IRMA Assay provided nearly identical results. As part of the guilty plea, NID admitted that in or about May 2000 and at various times thereafter, the company knowingly, intentionally and with intent to mislead, introduced into interstate commerce, and caused the introduction into interstate commerce of the Advantage Intact PTH Assay, that was misbranded.

The civil settlement resolves allegations that NID manufactured, marketed and sold the Intact PTH and Bio-Intact PTH test kits, despite knowing that between May 1, 2000, and April 30, 2006, some of these kits produced results that were materially inaccurate and unreliable, thereby causing: (a) some clinical laboratories that purchased and used the Intact PTH and Bio-Intact PTH test kits to submit false claims for reimbursement to federal health programs; and (b) some medical providers to submit false claims for reimbursement to federal health programs for unnecessary treatments.

The civil settlement also resolves allegations that NID manufactured, marketed and sold test kits, some of which produced results that were materially

inaccurate and unreliable, thereby causing some clinical laboratories that purchased and used these test kits to submit false claims for reimbursement to federal health programs.

"This settlement provides further evidence that the Department will vigorously prosecute cases involving violations of the Food, Drug, and Cosmetic Act, and will pursue recovery of taxpayer dollars resulting from fraudulent marketing campaigns by medical device manufacturers," said Michael F. Hertz, Acting Assistant Attorney General for the Civil Division. "Pursuing this case was particularly important in light of the potential for adverse health consequences to beneficiaries of federal healthcare programs."

"The American public has the right to expect medical device manufacturers to make accurate claims in their labeling, especially when the failure to meet those claims could indicate that the performance of the device is suspect," stated U.S. Attorney Benton J. Campbell. "In order to safeguard public health, and when appropriate, to recover taxpayer dollars, the government will vigorously investigate allegations that a manufacturer knowingly sold medical devices, such as test kits, that were materially unreliable or provided significantly inaccurate results."

Besides the Justice Department's Civil Division and the U.S. Attorney's Office for the Eastern District of New York, the Department of Health and Human Services Office of Inspector General; FBI: U.S. Postal Inspection Service; and the Food and Drug Administration, Office of Criminal Investigations assisted in the matter.

SOURCE U.S. Department of Justice

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